II. REMARKS

Claims 11-20 are pending in this application. Claims 11-20 are amended for clarification. The broadening amendments are supported by the originally filed specification and claims. For example, the broadening amendments to claims 1 and 17-18 are supported by paragraph [0059] and Table 2 of the specification. No new matter is added.

Claims 11-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 59-66 of co-pending Application Serial No. 11/417,155 ("the '155 application") in view of Ammon et al. (European Patent No. EP 552657) in view of Balch et al. (Prescription for Nutritional Healing, 2nd Ed. Avery Publishing, garden City Park, NY (1997) pp. 452-455) in view of Yegorova (U.S. Patent Appl. Pub. No. 2002/0176900). This rejection is traversed.

Present independent claim 11 discloses "[a] method of treating psoriasis . . . comprising the steps of: a) orally administering . . . a composition comprising boswellic acid and a selenium compound . . . ; and b) topically applying . . . a composition of boswellic acid . . . ."

Applicants respectfully submit that none of the cited references, alone or in combination thereof, teach or suggest the unexpected results of the combination of an orally administered composition of boswellic acid and a selenium compound and topical application of a composition of boswellic acid as in the presently claimed invention. As noted by the Examiner in the Office Action, "[t]he claims of '155 do not specifically teach wherein the boswellic acid derivatives are combined with selenium compounds such as

selenomethinione to be taken orally, while concurrently applying boswellic acid to the skin for treatment of psoriasis, nor the particular amount of boswellic acid derivatives or selenium compounds" (Office Action, page 3) and "Ammon et al. did not teach the incorporation of selenium such as selenomethionine for treatment of psoriasis nor the particular dosage amounts of boswellic acid derivatives and selenium compounds" (Office Action, page 7). Applicants respectfully submit that Balch et al. and Yegorova do not satisfy the deficiencies of the '155 application and/or Ammon et al., as they merely relate to selenium and do not teach or suggest the combination of selenium and boswellic acid, much less the method of the present claims or the unexpected results thereof.

Applicants enclose a Declaration comparing the effects on symptoms of plaque psoriasis of a combined treatment of oral Boswellia serrata extract and a selenium compound and topical Boswellia serrata extract (i.e, within the scope of the present claims) with alternative treatments outside the scope of the present claims, such as placebo, oral Boswellia serrata extract alone, oral and topical Boswellia serrata extract, or oral selenium compound alone. As noted in paragraph 6 and Table 4 of the Declaration, individuals treated with an embodiment of the method of the present claims (treatment group D) had a significant and beneficial reduction in mean Psoriasis Area and Severity Index ("PASI") scores. The unexpected efficacy in these patients was far beyond any expected additive effect of the individual treatment components (i.e., a 5.9 reduction in mean PASI scores in Treatment Group D between baseline and final scores after subtraction of the placebo effect, as compared to a 3.1 reduction in PASI

scores after combining the effects seen in, for example, Treatment Group C (oral and topical Boswellia serrata extract) and Treatment Group E (oral selenium compound) after subtraction of the placebo effect from each group). Further, the Tables 2A-2D disclose unexpected and substantial decreases in Treatment Group D with biochemical assays of markers in each treatment group that further substantiates the mean PASI score data in Table 4. For example, Tables 5A, 5B, and 5D of the Declaration disclose an unexpected and substantial reduction in Tumor Necrosis Factor Alpha ("TNF Alpha"), Vascular Endothelial Growth Factor ("VEGF"), and Leukotriene B4 ("LTB4") in Treatment Group D, as compared to the other treatment groups, and Table 5C discloses an unexpected and substantial reduction in Prostaglandin E2 ("PGE2") in Treatment Group D, as compared to Treatment Groups B and C. Applicants submit that this evidence of unexpected results of the claimed method is more than sufficient to overcome the *prima facie* case of obviousness asserted by the Examiner.

Accordingly, for at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the provisional rejection of claims 11-20 on the ground of nonstatutory obviousness-type double patenting over claims 59-66 of the '155 application in view of Ammon et al., Balch et al., and Yegorova.

Claims 11-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ammon et al. (European Patent No. EP 552657) in view of Balch et al. (Prescription for Nutritional Healing, 2nd Ed. Avery Publishing, garden City Park, NY (1997) pp. 452-455) in view of Yegorova (U.S. Patent Appl. Pub. No. 2002/0176900). This rejection is traversed.

As noted above, present independent claim 11 discloses "[a] method of treating psoriasis . . . comprising the steps of: a) orally administering . . . a composition comprising boswellic acid and a selenium compound . . . ; and b) topically applying . . . a composition of boswellic acid . . . ."

Applicants respectfully maintain that none of the cited references, alone or in combination thereof, teach or suggest the unexpected results of the combination of an orally administered composition of boswellic acid and a selenium compound and topical application of a composition of boswellic acid as in the presently claimed invention. As noted by the Examiner in the Office Action, "Ammon et al. did not teach the incorporation of selenium such as selenomethionine for treatment of psoriasis nor the particular dosage amounts of boswellic acid derivatives and selenium compounds" (Office Action, page 7). Applicants respectfully submit that Balch et al. and Yegorova do not satisfy the deficiencies of Ammon et al., as they merely relate to selenium and do not teach or suggest the combination of selenium and boswellic acid, much less the method of the present claims or the unexpected results thereof.

As discussed above, the enclosed Declaration compares the effects on symptoms of plaque psoriasis of a combined treatment of oral Boswellia serrata extract and a selenium compound and topical Boswellia serrata extract (i.e, within the scope of the present claims) with alternative treatments outside the scope of the present claims, such as placebo, oral Boswellia serrata extract alone, oral and topical Boswellia serrata extract, or oral selenium compound alone. As noted in paragraph 6 and Table 4 of the Declaration, individuals treated with an embodiment of the method of the present claims

(treatment group D) had a significant and beneficial reduction in mean Psoriasis Area and Severity Index ("PASI") scores. The unexpected efficacy in these patients was far beyond any expected additive effect of the individual treatment components (i.e., a 5.9 reduction in mean PASI scores in Treatment Group D between baseline and final scores after subtraction of the placebo effect, as compared to a 3.1 reduction in PASI scores after combining the effects seen in, for example, Treatment Group C (oral and topical Boswellia serrata extract) and Treatment Group E (oral selenium compound) after subtraction of the placebo effect from each group). Further, the Tables 5A-5D disclose unexpected and substantial decreases in Treatment Group D with biochemical assays of markers in each treatment group that further substantiates the mean PASI score data in Table 4. For example, Tables 5A, 5B, and 5D of the Declaration disclose an unexpected and substantial reduction in TNF Alpha, VEGF, and LTB4 in Treatment Group D, as compared to the other treatment groups, and Table 5C discloses an unexpected and substantial reduction in PGE2 in Treatment Group D as compared to Treatment Groups B and C. Applicants submit that this evidence of unexpected results of the claimed method is more than sufficient to overcome the *prima facie* case of obviousness asserted by the Examiner.

Accordingly, for at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 11-20 under 35 U.S.C. § 103(a) over Ammon et al., Balch et al., and Yegorova.

III. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this paper is not considered to be timely filed, Applicant hereby petitions for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, referring to Attorney Docket No. **108064-00196**. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, referencing Attorney Docket No. **108064-00196**.

Respectfully submitted,

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Enclosure: Declaration